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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,249 04/10/2006 Pierre-Etienne Chabrier de Lassauniere 58767.000012 7098

21967 7590 11/14/2007

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WASHINGTON, DC 20006-1109

EXAMINER
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ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
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1626

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11/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/575,249

Applicant(s)

CHABRIER DE LASSAUNIERE ET AL.

Examiner

Rebecca L. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 6-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☒ Claim(s) 1, 4 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/089993 and 10/915001.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/13/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-10 are currently pending in the instant application. Claims 2 and 6-10 are withdrawn from consideration as being for non-elected subject matter. Claims 1, 4 and 5 are objected. Claims 1 and 3-5 are rejected.

### ***Election/Restrictions***

Applicant's election with traverse of Group II in the reply filed on 11 September 2007 is acknowledged. The traversal is on the ground(s) that there is no undue burdensome search. This is not found persuasive because the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner. Applicant also argues that according to 37 CFR 1.475(b) that groups II and III and I and IV are to be examined together. This argument is not persuasive as the claims are drawn to more than a product and more than one process of using the product as can be seen by the various compounds listed in claim 1 which differ materially in structure and composition. Additionally, Groups I-IV lack unity of invention since under 37 CFR 1.475: the technical features corresponding to the claims are 4-phenylthiazole and 4-phenylimidazole. These technical features are not special technical features because they fail to define a contribution over the prior art as can be seen, for example, by WO 98/58934. Therefore claims 1-10 are not so linked

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as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature as the technical features present fail to define a contribution over the prior art. Furthermore, as seen by the following prior art rejections, the claims as presented lack unity as the technical feature present in the claims is not a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119 (a)-(f) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date as follows: Specifically, applicant is claiming priority benefit on the declaration and application data sheet under 35 USC 119(a)-(d) or (f) to US Patent Application No.'s 10/681,002 and 10/915,001 which are not foreign applications. Applicants' filing receipt mailed 11/29/06 lists priority as:

**Domestic Priority data as claimed by applicant**

This application is a 371 of PCT/FR04/02537 10/08/2004  
which is a CON of 10/681,002 10/08/2003  
which is a CIP of 10/089,993 04/04/2002  
which is a 371 of PCT/FR00/02805 10/10/2000  
This application 10/575,249  
is a CON of 10/915,001 08/10/2004  
which is a CIP of 10/681,002 10/08/2003  
which is a CON of PCT/FR02/01218 04/09/2002  
which is a CIP of 10/089,993 04/04/2002  
which is a 371 of PCT/FR00/02805 10/10/2000

**Foreign Applications**

FRANCE 99 12643 10/11/1999

FRANCE 00/10151 08/01/2000  
FRANCE 00/11169 09/01/2000  
FRANCE 01/04943 04/10/2001  
FRANCE 02/01811 02/14/2002  
FRANCE PCT/FR02/01218 04/09/2002  
FRANCE 99/12643 10/11/1999

In regards to the foreign priority, it is noted that copies of FR PCT/FR02/01218 04/09/2002 and FR 99/12643 are not found in this or a prior application. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in a parent application under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be timely made in this application. To satisfy the requirement of 37 CFR 1.55(a)(2) for a certified copy of the foreign application, applicant may simply identify the application containing the certified copy.

In regards to the domestic priority, it is noted again that US Patent Application 10/681,002 and US Patent Application 10/915,001 are not foreign documents. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the

application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference

was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Additionally, in regards to US Patent Application No.'s 10/681,002 and 10/915,001 of which the filing receipt states that the instant application is a continuation of, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed applications, Application No. 10/681,002 and 10/915,001, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, claims 1, 3, 4 and 5 do not find support in the previous applications and therefore only receive the benefit of priority to the date of PCT/FR04/02537 filed 8 October 2004. The subject matter found in claims 1, 3, 4 and 5 which does not find support in the previous applications is for example the 2<sup>nd</sup>, 6<sup>th</sup>-8<sup>th</sup>, 10<sup>th</sup>-28<sup>th</sup> compounds of claim 1. These compounds are either found nowhere in the prior application or are

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found only as an HCl salt. For example, the compound 4-[2-(1-aminocyclopentyl)-1,3-thiazol-4-yl]-2,6-di-tert-butylphenol is found nowhere in Application No. 10/681,002 and only the HCl salt of 4-[2-(1-aminocyclopentyl)-1,3-thiazol-4-yl]-2,6-di-tert-butylphenol is found in 10/915,001 which does not provide support to a claim to the compound and any salt thereof. Accordingly, claims 1, 3, 4 and 5 are not entitled to the benefit of the prior applications 10/681,002 and 10/915,001.

This application repeats a substantial portion of prior Application No. 10/681,002 and 10/925,001 filed 10/8/03 and 8/10/04, respectively, and adds and claims additional disclosure not presented in the prior applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

It is requested that applicant provide clarification as to what priority is claimed.

### ***Claim Objections***

Claims 1, 4 and 5 are objected to as containing non-elected subject matter. Claims 1, 4 and 5 presented drawn solely to the elected invention of Group II would overcome this objection.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory



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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35, 37, 38, 50 and 51 of copending Application No. 10/681/002. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claim 35 generically overlaps with applicants instantly claimed invention and provides

preferences wherein n is 0-2 in conflicting claim 37 and wherein R1 and R2 are hydrogen (conflicting claim 38). Conflicting claims 50 and 51 provide the compound and pharmaceutical composition of 4-[2-(aminomethyl)-1,3-thiazol-4-yl]-2,6-di(tert-butyl)-phenol which differs from applicants invention by an aminomethyl instead of an aminoethyl. Additionally, page 99 of the specification provides that the compounds can contain asymmetrical carbon atoms and that the present invention includes the two enantiomeric forms and all combinations of these forms, including the racemic "RS" mixtures. Therefore, the difference between the conflicting claims and applicants' instant claims is a difference in homologs. To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/083656. WO 02/083656 discloses compounds useful for the inhibition of monoamine oxydase for the treatment of diseases such as pain (abstract). For

example, WO 02/083656 discloses the last listed compound of claim 7, N-2-dimethyl-1-[4-(10H-phenothiazin-2-yl)-1,3-thiazol-2-yl]propan-1-amine which corresponds to the 2<sup>nd</sup> listed compound of claim 1 and 4.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by 7,291,641 which discloses compounds for the treatment of diseases such as pain (abstract). For example, 7,291,641 discloses compounds such as example 496 which is the hydrochloride salt of 4-[2-(1-aminocyclopentyl)-1,3-thiazol-4-yl]-2,6-di-tert-butylphenol.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0132788 or WO 01/26656.

***Determining the scope and contents of the prior art.***

US Pre-Grant Publication 2004/0132788 discloses or WO 01/26656 disclose compounds useful for the treatment of diseases such as pain (abstract). For example, the prior art references disclose the compound 4-[2-(aminomethyl)-1,3-thiazol-4-yl]-2,6-di(tert-butyl)phenol (claim 45 US 2004/0132788 or page 237 of WO 01/26656).

***Ascertaining the differences between the prior art and the claims at issue***

Additionally, page 44 of the Pre-Grant publication or page 71 of the WO disclose that the compounds can contain asymmetrical carbon atoms and that the present invention includes the two enantiomeric forms and all combinations of these forms, including the racemic "RS" mixtures. Therefore, the difference is a difference in homologs.

***Resolving the level of ordinary skill in the pertinent art.***

To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The motivation would be to prepare additional compounds useful for the treatment of diseases such as pain.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Rebecca Anderson/  
Primary Examiner, AU 1626*

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Technology Center 1600

8 November 2007